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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, Fl 32751

VIA FEDERAL EXPRESS

WARNING LETTER

FLA-02-25

January 29, 2002

Paul D. Schuman, President/CEO
Optical Polymer Research, Inc.
5921 N.E. 38th Street
Gainesville, Florida 32609

Dear Dr. Schuman:

During an inspection of your establishment located in Gainesville, Florida on December 6-7, 2001, FDA Investigator R. Kevin Vogel determined that your establishment is a manufacturer and distributor of rigid, gas permeable contact lens and soft contact lens blanks. Under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), contact lens blanks are medical devices that are used to diagnose or treat medical conditions or to affect the structure or function of the body. During the inspection, the investigator documented violations of the Act causing the device to be adulterated within the meaning of section 501(h) of the Act. The Act requires that manufacturers conform to the Quality System (QS) Regulation for medical devices, as specified in Title 21, Code of Federal Regulations (CFR), Part 820.

The above-stated inspection revealed that the device is adulterated in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Quality System Regulation as follows:

1. Your firm failed to conduct quality audits at sufficient intervals as listed in your own procedures to verify that the quality system is effective as required by 21 CFR 820.22. Quality audits conducted were not documented to allow review, quality audit procedures are incomplete, e.g., personnel qualification, design control, corrective and preventive actions are not addressed (FDA 483, Observation #7) and annual audits of finished lens laboratories have not been completed on an annual basis pursuant to written procedures (FDA 483, Observation #8).

2. Your firm failed to maintain complaint files as required by 21 CFR 820.198(a). For example, complaints received are not documented (FDA Observation, #1).

3. Your firm failed to analyze all sources of quality data to identify existing and potential causes of nonconforming product and other quality problems as required by 21 CFR 820.100(a)(1). For example, there is no trend analysis of in-process rejects over time (FDA 483, Observation #5).

4. Your firm failed to establish procedures covering documentation of corrective and preventive action as required by 21 CFR 820.100(b). For example, written corrective and preventive action (CAPA) procedures fail to address analysis of all quality data to determine the need for corrective and preventive action and verification/validation to ensure actions taken are not detrimental to finished devices (FDA 483, Observation #6).

5. Your firm failed to establish design control procedures as required by 21 CFR 820. 30(a). For example, there are no design control procedures covering devices, packaging and labeling processes (FDA 483, Observation #3).

6. Your firm failed to establish and maintain a design history file, as required by 21 CFR 820.30(j). For example, design changes covering the addition of new green tint to the O-Perm 30 contact lens blanks, including risk analysis is not documented (FDA 483, Observation #2).

7. Your firm failed to develop, conduct, control, and monitor production processes to ensure that a device conforms to its specifications as required by 21 CFR 820.70(a)(4). For example, there is no documentation of personnel qualification concerning manufacturing/inspection related to center grinding operations and base curve/power inspection (FDA 483, Observation #4).

MEDICAL DEVICE REPORTING

Your devices are also misbranded within the meaning of section 502(t)(2) in that there was a failure to furnish material or information required by or under section 519 respecting the devices. These violations include, but are not limited to the following:

8) Your firm failed to develop, maintain, and implement written MDR procedures as required by 21 CFR 803.17 (FDA 483, Observation #9).

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of

contracts. Additionally, no premarket submissions for Class III devices to which QS regulation deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates for Products for Export will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within fifteen (15) working days of receipt of this letter, of any steps you may have taken to correct the noted violations, including (1) the time frames within which the corrections will be completed, if different from those annotated on the FDA 483, (2) any documentation indicating the corrections have been achieved, and (3) an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur.

Your response should be sent to Timothy J. Couzins, Compliance Officer, Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, (407) 475-4728.

Sincerely,

Emma Singleton
Director, Florida District